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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,340	03/30/2004	Jay A. Berzofsky	015280-368240US	8261

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EXAMINER	
KINSEY, NICOLE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,340	BERZOFSKY ET AL.	
	Examiner	Art Unit	
	Nicole E. Kinsey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-42 and 44-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21,23-42 and 44-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:1, classified in Class 424, subclass 85.6.

II. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:3, classified in Class 424, subclass 85.6.

III. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:4, classified in Class 424, subclass 85.6.

IV. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:5, classified in Class 424, subclass 85.6.

V. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:6, classified in Class 424, subclass 85.6.

VI. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:7, classified in Class 424, subclass 85.6.

VII. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:8, classified in Class 424, subclass 85.6.

VIII. Claims 1-16, 21, 23, 25-37, 42, 44, drawn to a method using HIV-I antigen SEQ ID NO:9, classified in Class 424, subclass 85.6.

IX. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:10, classified in Class 424, subclass 85.6.

X. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:11, classified in Class 424, subclass 85.6.

XI. Claims 1-16, 21, 24-37, 42, 45, drawn to a method using HIV-I antigen SEQ ID NO:12, classified in Class 424, subclass 85.6.

XII. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:13, classified in Class 424, subclass 85.6.

XIII. Claims 1-16, 21, 25-37, 42, drawn to a method using HIV-I antigen SEQ ID NO:14, classified in Class 424, subclass 85.6.

XIV. Claims 1-15, 17, 25-36, 38, drawn to a method using influenza antigens, classified in Class 424, subclass 85.6.

XV. Claims 1-15, 18, 25-36, 39, drawn to a method using rotavirus antigens, classified in Class 424, subclass 85.6.

XVI. Claims 1-14, 19, 25-35, 40, drawn to a method using pathogenic bacterium or protozoan, classified in Class 424, subclass 85.6.

XVII. Claims 1-14, 20, 25-35, 41, drawn to a method using tumor-associated antigens, classified in Class 424, subclass 85.6.

XVIII. Claims 46-69, drawn to a composition comprising a purified soluble antigen, classified in Class 424, subclass 184.1.

Inventions I-XVII are directed to related subject matter (i.e., methods of inducing mucosal immunity). The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, each method is distinct from the other because they each have a materially different design (each method requires a structurally different antigen) and effect (the resulting immunity is specific for each antigen used). Furthermore, the inventions as claimed do not overlap in scope (i.e., the antigens do not overlap in structure of effect) and there is nothing of record to show them to be obvious variants.

In addition to their distinctness, searching the inventions of groups I-XVII would impose a serious search burden. Even though groups I-XVII are identically classified under U.S. Patent Classification guidelines, the search required for any one group is not required for any other group. Thus, a separate search is required for each group, which would impose a serious search burden on the Examiner. Therefore, because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02) resulting in a serious search burden on the Examiner, restriction for examination purposes as indicated is proper.

Inventions XVIII and I-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process of inducing mucosal immunity can be practiced with another materially different product, such as DNA vaccine. It is known in the art that DNA encoding the antigen of interest can be administered to mucosal tissue. The DNA molecules are taken up by the cells in the mucosal tissue, and the protein/antigen encoded by the DNA is expressed. The expression of the protein in the cells of the mucosal tissue results in the induction of a mucosal immune response. Thus, it is not necessary to use a composition of a purified soluble antigen to induce mucosal immunity.

In addition to their distinctness, searching the inventions of groups XVIII and I-XVII would impose a serious search burden. The groups are not identically classified under U.S. Patent Classification guidelines, and the search required for group XVIII is not required for any invention of groups I-XVII, and vice versa. Thus, a separate search is required, which would impose a serious search burden on the Examiner. Therefore, because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02) resulting in a serious search burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E Kinsey, Ph.D.
Examiner
Art Unit 1648

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